

Sammendrag af EP 0737467 (A1)

At least one cannula (8) is mounted in the hollow body (3) so as to move in its longitudinal direction, and pierces the closure stopper closing the receptacles. The cannula is mounted in a plate-shaped holder (9) pointing at right angles to the longitudinal direction (31) of the hollow body. The holder is joined to the inner wall (30) of the hollow body by holder arms (13) which can be severed on the application of manual force greater than the penetration force of the cannula when piercing the closure stopper of the first receptacle (1).


[Description of EP0737467](#)
[Print](#)
[Copy](#)
[Contact Us](#)
[Close](#)

Result Page

Notice: This translation is produced by an automated process; it is intended only to make the technical content of the original document sufficiently clear in the target language. This service is not a replacement for professional translation services. The esp@cenet® Terms and Conditions of use are also applicable to the use of the translation tool and the results derived therefrom.

Die Erfindung betrifft eine Vorrichtung zum Zusammenführen einer ersten flüssigen und einer zweiten festen oder flüssigen Komponente mittels Unterdruck unter sterilen Bedingungen, mit einem die erste Komponente aufnehmenden ersten Behälter und einem die zweite Komponente aufnehmenden, unter Unterdruck stehenden zweiten Behälter, sowie einem zylindrischen Hohlkörper zur Aufnahme des ersten Behältnisses im Bereich dessen Verschlusses in einer ersten Hohlkörperöffnung und einer zweiten, diametral zu dieser angeordneten Hohlkörperöffnung, zur Aufnahme des zweiten Behältnisses im Bereich dessen Verschlusses, sowie mindestens einer im Hohlkörper gelagerten und in dessen Längsrichtung verschiebbaren Kanüle zum Durchstechen der die Behältnisse jeweils verschliessenden Verschlussstopfen, wobei die Kanüle in einem Kanülenträger gelagert ist.

A such device, the component of a preassembled system for the transition of liquids forms, is from the DE 38 17 101 A1 known. The system allowed it to bring the second container with the attached device in the commerces so that for leading up liquid to this second container the first container must be only attached to the unit formed by the second container and the device. The slidable storage of the cannula in the hollow body and a over traction resistance rising up into the path of the Kanülenträgers place safer the fact that the second container inserted into the hollow body is with this connected but not in contact with the cannula arrives. Only after puncturing the liquid the female first container becomes with the other insertion of the container connecting piece of the first container the over traction resistance over-driven and that plug of the second container pierced, with which the interior of the two containers is connected by means of the cannula.

With the known device is both at the Kanülenträger and at component of the hollow body a formed bearing sleeve a circumferential projection provided. With the contact of the two projections the resistance for the over driving of the bearing sleeve-lateral Vorsprunges, resultant, is large as the penetrating resistance of the cannula with the ingress into the plug of the first container. Adverse one is here that the formation of the parts with the projections requires an exact calculation of projection/lead outside diameter of the Kanülenträgers and projection/lead inside diameter of the bearing sleeve, in order to obtain timed abfolgende puncturing that plug of the containers. The projections involve an increased manufacturing expenditure of the device, related to the production of the Kanülenträgers and the hollow body, in all other respects is in all other respects the assembly of the device in the region of the Kanülenträgers right expensive.

It is object of the instant invention to form a device for that initially mentioned type so more other that this with structural simple design a straightforward confound-safe and not reversible handling possible.

Dissolved one becomes the object with a device that initially mentioned type by the fact that the Kanülenträger is formed as plate shaped, vertical body oriented to the longitudinal direction of the hollow body, which is over retaining bars with the inner wall of the hollow body connected, whereby the retaining bars are tear upable by applying a manual force, those is larger as the penetrating strength of the cannula when puncturing the plug of the first container.

Thereby the Kanülenträger before the a stinging of the cannula becomes according to invention into the plug of the second container by means of the plate shaped retaining bars at the inner wall of the hollow body fixed. A displacement of the cannula is therefore possible only if the retaining bars became torn by applying the manual force before. It is thereby a safe sequential sequence of the movement ensured. The formation of the device possible their simple design, by it, if necessary up to the cannula, when plastic injection moulding part is designed.

In accordance with a particular embodiment of the invention is provided that the Kanülenträger is also connected on the inner wall of the hollow body to directed guidance beginnings. These make after the separation of the retaining bars a to a large extent tilt-free guide of the Kanülenträgers for relative possible to the inner wall of the hollow body, thus a to a large extent exact guide of the cannula in the Einstechbereich to the second container, whereby the cannula is besides in the plug of the first container held.

The hollow body favourably exhibits an opening with circular cross-section. In particular with such a design triangle or circular formation of the Kanülenträgers offers itself to the hollow body opening. The Kanülenträger exhibits for example the form of an equilateral triangle, with three guidance beginnings, which are in the region in the middle of the triangle sides of the Kanülenträgers with this connected. With a circular Kanülenträger are preferred four in each case to each other disposed guidance beginnings at the periphery of the Kanülenträgers with this connected, offset around 90 degree. The guidance beginnings can exhibit themselves radial outer

▲ top

concentric to the cannula and in longitudinal direction of the hollow body extending guidance flags.

A preferred development of the invention plans that are connected with the inner wall of the hollow body in its longitudinal direction longitudinal guidance beginnings, between which the guidance beginnings or the corners of the Kanüenträgers disposed is. The respective guidance beginning should be thereby over a central web with the Kanüenträger connected and rear-seize in each case two guidance beginnings the guidance beginning in the region of the central web. The design of the hollow body with guidance beginnings a conditional defined positioning of the Kanüenträgers relative to the hollow body during its displacement in longitudinal direction and prevented thereby also a relative rotation and/or. tilting the Kanüenträgers to the hollow body.

For improving the guide of the container in the hollow body, this is favourably in the region at least an end parallel to the container extended which can be taken up by the associated hollow body opening. The extension effected that the container is not only in the region the plug of exhibiting container neck held, but the extended portion of the hollow body also, the bulky region of the container at least partly with more or few, widened in all rule, large distance surrounds, so that tilting of the container is in the hollow body excluded. Of importance this is for the container, that in particular the substance bottom vacuum and/or. Vacuum conditions takes up, so when leading up the liquid to this container active guided does not have to become, but this only with the other one, the liquid female container required is. Convenient one exhibits the extended portion of the hollow body an inside diameter, which is larger slight as the outer diameters of the container. It becomes thereby not only inadvertent tilting of the container prevented, but the container defined guided.

It is provided in particular that the device with the two containers forms a preassembled, sterile packaged system, with which the two containers except contact with the cannula in the cylindrical hollow body held is and a packaging means includes the containers and the hollow body sterile.

After the transition of the liquid bottom sterile ratios is in a Umverpackung possible, stand thereby a leading up system make possible and a package for the order, which significant simplify, accelerate the preparation of the components located in the containers and permit a complete separated preparation timed of the immediate application, as well as a storage of the reconstituted components over several days. The design and arrangement of the leading up system a possible quick, safe, confound-free and reversible transition of the component into that, located in the first container, the other component contained second container bottom lowest possible effort for the user and bottom maintenance of the sterility also after that did not bring together the components.

Other features of the invention are in the Unteransprüchen, the description of the figs and the figs themselves shown, whereby noted becomes that all single characteristics and all combinations of single characteristics are invention-substantial.

In the figs the invention is for example shown on the basis several embodiments, without being on these limited. It shows in schematic representation:

Fig 1 the fundamental structure of a preassembled leading up system using the leading up device, in a longitudinal section by the device shown,
Fig 2 the preassembled leading up system in accordance with fig 1, which is received of a sterile Umverpackung,

Fig 3a a reduced illustration of the preassembled leading up system, i.e. before puncturing the first container,
Fig 3b the leading up system after fig 3a after puncturing the first container,
Fig 3c the leading up system in accordance with the figs 3a and 3b, after puncturing the second container,
Fig 4a an enlarged view in fig 1 of the leading up device shown, in a prolonged middle section illustrated,
Fig 4b a section by the embodiment after fig 4a, vertical to longitudinal axis the cannula in the region of the Kanüenträgers cut,
Fig 5a one opposite the embodiment after the figs 4a and 4b modified design of the device, in a prolonged middle section,
Fig 5b a section by the embodiment after fig 5a, vertical to longitudinal axis the cannula in the region of the Kanüenträgers cut,
Fig 6a an other, opposite the embodiment after the figs 4a and 4b modified design of the device, in a prolonged middle section seen,
Fig 6b a section by the embodiment after fig 6a, vertical to longitudinal axis the cannula in the region of the Kanüenträgers cut,
Fig 7a an other design of the device, in a prolonged middle section seen, modified opposite the embodiment after fig 6a, with both-end to introduced, partly represented containers and
Fig 7b a section in accordance with the line A-A in fig 7a.

Fig 1 shows a cylindrical hollow body 3, whose exhibits both hollow body openings 6 and 7 same inside diameter. On the orientation the receptacle a liquid serves the fig 1 based upper hollow body opening 6 of a female bottle 1, the bottom opening 7 of the receptacle a substance bottom vacuum and/or. Vacuum conditions female bottle 2. The opening of the respective bottle 1 and/or. rubber stoppers not shown, that locks 2 by means of a flange cap 4 and/or. 5 held is. In the region of the respective flange cap 4 and/or. 5 is the bottle 1 and/or. 2 into the hollow body 3 inserted and of this held. For instance in the region of the half length of the hollow body 3 a plate shaped Kanüenträger is 9 within the hollow body 3 disposed, which is vertical to the central longitudinal axis 31 of the hollow body 3 positioned. The Kanüenträger 9 is connected solid with the inner wall 30 of the hollow body 3 over several radial longitudinal retaining bars 13. The Kanüenträger 9 exhibits a through hole to the receptacle of a cannula 8, whose passage axle coincides with the central longitudinal axis 31.

The bottle 2 contacted after putting into the hollow body 3 with the inner wall 30 of the hollow body of 3 connected abutments 10, so that it can not more other be inserted toward the cannula 8 into the hollow body 3,

▲ top

but rather between the associated inner wall section of the hollow body 3 clamped is. Those the liquid female bottle 1 however is in a preassembled position in the actual hollow body opening range a directed portion of the hollow body 3 held, whereby parallel inner annular bead 33 oriented to the Kanüenträger 9 rises up into the shifting way of the flange cap 4 and thus the mounting position is defined. In position and the preassembled from the two bottles, shown in fig 1, of the 1 and 2 and the hollow body of 3 leading up system formed with Kanüenträger 9 and cannula 8 the flange caps 4 and 5 and thus the rubber stopper are for locking the bottles 1 and 2 in slight distance to the two ends of the cannula 8. In this state the leading up system becomes already sterilized with the pharmaceutical manufacturer into a peelbare Umverpackung 14 in-sealed and, as it is in fig 2 illustrated. This Umverpackung 14 consists of a deep-drawable Weichblisterfolie, preferably PA/PE and a sterilizable, sealable medical paper or a polyethylene spin fleece. After that a seals of the labeled and mounted units a made sterilization for example with ethylene oxide. In a corresponding designed secondary packing the user accomplishes then the preparation of the components in the sterile Umverpackung, bottom maintenance of the sterility despite puncturing the respective containers.

The figs 3a to 3c clarify the procedures, in order to unite the components. Fig 3a the illustrated preassembled system, as it is in fig 1 shown. Outgoing one of it is slid those the liquid female bottle 1 of other into the hollow body 3, whereby the cannula 8 penetrates the plug of the bottle 1, which of rubber consists. This is possible, because the penetration and/or. Penetrating strength of the cannula 8 in and/or. by the rubber stopper of the bottle 1 is smaller than the force, which is required, in order to separate the Kanüenträger 9 tied up over the retaining bars 13 to the hollow body 3 from this to. In the advanced position shown in fig 3b the flange cap 4 arrives to the bottle 1, with which the cannula 8 has the rubber stopper pierced, to this bottle 1 in plant with the Kanüenträger 9, with which the manual 1 pushing in strength applied on the bottle becomes the insertion of the bottle 1 9 transferred into the hollow body 3 immediate on the Kanüenträger. When applying a corresponding high manual force the retaining bars 13 tear, so that the bottle becomes more other 1 together with the Kanüenträger 9 and thus the cannula 8 toward the bottle 2 within the hollow body 3 displaced, so that the cannula 8 punctures the rubber stopper of this bottle 2. The vacuum located in the bottle 2 sucks the liquid from the bottle 1 into the bottle 2 and leads to the resolution and/or. Mixing in this located solid and/or. liquid Komponente. Das system also in leading up position located cannula 8 is in fig 3c shown.

The figs 4a and 4b illustrate in the figs 1 to 3c to the leading up system the described device to brought together the components in the detail. With this embodiment of the device the hollow body 3 is in the region of the hollow body opening 6 as collar 34 with only connected with one another retaining bars 16 formed by thin places. Thereby it is possible to use bottles of 1 different volume for example all injection bottles from 6 to 100 ml, since only possible one when activating the bottle 1 with a nominal value of large/same 10 ml an insertion is into the hollow body 3, if the ring first used to the fixation is blown up and the larger body diameter of the bottle 1 place offers.

How is to be taken in particular 4b from the illustration of the fig, the Kanüenträger 9 exhibits the form of a circle and is essentially provided with four guidance beginnings 35, which are offset with this connected, at the periphery of the Kanüenträgers 9 around in each case 90 DEG, to each other. The guidance beginnings 35 exhibit themselves radial outer concentric to the cannula 8 and in longitudinal direction of the hollow body 3 extending guide surface 36. This is in short distance to the inner wall 30 of the hollow body 3 disposed, so that the Kanüenträger is 9 after tearing the retaining bars 13 up free from play and thus nontilting in the hollow body 3 relocatable. The hollow body 3 is inside with four, in longitudinal direction of the hollow body 3 longitudinal, in each case over 90 DEG to each other offset disposed ribs 37 in all other respects provided, which give the photograph diameter of the hollow body 3 for the bottle 1 and so that ensures an exact positioning of the bottle 1, whereby the insertion of this bottle 1 can take place because of their plant with their flange cap 4 at the ribs 37 with small energy expenditure. The ribs 37 intersperse recesses 38 between the guidance beginnings 35.

With the reference numeral 15 is in the plane of the abutments 10 disposed and with the interior of the hollow body 3 connected retaining bar designated, that after the reconstitution of the components with the withdrawal of the bottle 2 from the hollow body 3 prevented that the Kanüenträger 9 of the hollow body 3 falls out and/or. the cannula 8 held in the Kanüenträger 9 in the rubber stopper of the bottle 2 to be remains.

With the embodiment after the figs the Kanüenträger 9 exhibits ä and 5b the form of an equilateral triangle and it is essentially three guidance beginnings 35 provided, which are in the region in the middle of the triangle sides of the Kanüenträgers 9 with this connected. With the inner wall 30 of the hollow body 3 longitudinal, wing-like guidance beginnings are 12 connected in its longitudinal direction, are 9 disposed between which the guidance beginnings 35 of the Kanüenträgers. The respective guidance beginning 35 is 9 connected and it over a central web 39 with the Kanüenträger rear-seizes in each case two adjacent guidance beginnings 12 the guidance beginning 35 in the region of the central web 39. Each guidance beginning 35 is over a retaining bar 13 with the hollow body 3 connected. The triangle dimension of the Kanüenträgers 9 is a so selected that its tips with minimum clearance are to the inner wall 30 of the hollow body 3 positioned, which applies in the rest of also to the position of guide surface 36 of the respective guidance beginning 35 and inner wall 30 of the hollow body 3. Adjacent guidance beginnings 12 are like that 30 divergent disposed to the inner wall that they take up a corner 40 of the Kanüenträgers 9 between itself.

▲ top

With the embodiment after the figs ä and 5b the made pre-assembly of the flange cap 4 of the bottle 1 on the guidance beginnings 12 to against the backjumping approaches 11 of the guidance beginnings 12. With the other insertion of this bottle 1 for puncturing the cannula 8 the guidance beginnings 12 arrived after radial outer bent, the flange cap 4 in plant with the Kanüenträger 9 and it are blown up when applying an increased manual force the retaining bars 13.

With the embodiment after the figs 7a and 7b exhibits the hollow body opening 7 (opposite the embodiment after fig 6a) a larger longitudinal extent. Achieved one becomes this by an extension the opening of the formed

ring portion 45 of the hollow body 3. The inside diameter of the ring portion is slightly larger sized as the outer diameters of the bottle 2 in the bottle section 46. With complete bottle 2 contacted this with their flange cap 5 the abutments 10 of the hollow body 3 enclosing inserted into the bottom opening 7 the rubber stopper, whereby the flange cap 5 is 47 guided by means of ribs, which are diametric with the inner wall 30 of the hollow body 3 connected. Fig 7 clarifies that the outer diameter of the flange cap 5 is smaller than the outer diameter of the container 2 and itself the ring portion 45 to the lateral flange portion 46 extended. Thereby tilting of the bottle is 2 in the hollow body opening 7 effectively prevented. The upper hollow body opening 6 is correspondingly formed, i.e. it made also there a guide of the bottle of 1 in the region their bottle section 46, thus their maximum widened region.

The leading up device in accordance with the figs 4a and 4b is suitable for injection bottles 1 and 2 with a nominal size of 20 mm. The leading up device after the figs 5a and 5b serves leading up a substance from a bottle 1 with a nominal size of 13 mm to a bottle 2 with a nominal size of 20 mm. With the embodiment after the figs 6a and 6b, those up to the design of the hollow body opening 7 identical is with the embodiment after the figs 7a and 7b, serves the device of the receptacle of bottles 1 and 2 with a nominal size of 13 mm. Also the embodiment after the figs 7a and 7b serves the receptacle of bottles 1 and 2 with a nominal size of 13 mm.